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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,971	09/24/2003	Nathan A. Winslow	5490-000337	4885

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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01/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/669,971

Applicant(s)

WINSLOW, NATHAN A.

Examiner

Javier G. Blanco

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 31, 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-11, 13-15, 17, 19-22, 24, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-11, 13-15, 17, 19-22, 24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Response to Amendment

2. Applicant's amendment of claims 1, 11, 19, and 27 in the reply filed on October 31, 2007 is acknowledged.

Claim Objections

3. Claims 26 and 27 are objected to because of the following informalities:
- a. Regarding claim 26, please substitute "the pair of planar surfaces" (see line 4) with --the pair of planar inner surfaces--. Appropriate correction is required.
 - b. Regarding claim 27, please substitute "the flange surface" (see line 3) with --the flange extended surface--. Appropriate correction is required.
 - c. Regarding claim 27, please substitute "the pair of planar surfaces" (see line 4) with --the pair of planar inner surfaces--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 19-22, 24, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 19, newly added limitation “positioning a resurfacing humeral head implant having an extended articulating surface protruding from only a portion of said resurfacing head”

(see line 9) is indefinite as to the scope of the invention. Is said extended articulating surface protruding from only a portion of the resurfacing head, or protruding only from a portion of a hemispherical exterior articulating surface of the implant? Said limitation will be broadly interpreted. Claims 20-22 and 24 depend on claim 19.

b. Regarding claim 27, the limitation “the flange exterior surface” (see line 2) lacks antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5, 7-11, 13, 14, 17, 19-22 and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sutter et al. (US 4,328,593 A).

Referring to Figures 1-14, Sutter et al. disclose a method (see Figures 4 and 5; see column 5, line 65 to column 6, line 28) for resurfacing a humeral head of an implant site.

The resurfacing humeral head implant comprising:

- (i) A hemispherical exterior articulating surface (e.g., cap 3);
- (ii) A concave interior surface (e.g., 3d, or inner cap surface; see Figures 1, 3, 6, 10, 11, and 14) opposite said exterior articulating surface;
- (iii) An integral (i.e., unitary, see column 9, lines 9-12) straight anchoring device (e.g., sleeve 7) having a textured outer surface (see column 5, lines 55-65), said anchoring device extending from said interior surface; and
- (iv) An extended articulating surface (e.g., 3c) protruding from only a portion (e.g., from the periphery) of said hemispherical exterior articulating surface (see Figure 3). It should be noted that, from the claim language, an arbitrary line or boundary distinguishes/defines the "extended articulating surface". Said extended articulating surface having a pair of interior intersecting planar surfaces (Figures 1-3, 7, 9, and 10: ribs 3g and grooves 3f; see column 4, lines 47-64; column 5, lines 32-53), said planar surfaces being generally parallel to the integral straight anchoring device (clearly seen in Figures 1-3; see column 4, lines 47-64; column 5, lines 32-53) and forming a "V" shaped surface (see Figures 2 and 7). Sutter et al. disclose ribs 3g and grooves 3f are used in order to permit the prosthesis to be firmly and durably secured without cement (among other advantages; see Abstract; see column 4, lines 47-64; column 5, lines 32-53).

The method comprising:

- (i) Resurfacing the humeral head so as to remove a portion of the humeral head (compare Figure 4 to Figure 5) leaving a resurfaced surface;

- (ii) Boring a hole (Figure 5: bore/hole 11c, which will accept sleeve 7) into the humeral head;
- (iii) Resecting a portion of the humeral head (Figure 5) so as to form a pair of intersecting planar surfaces (see column 6, lines 12-15); another possible interpretation for “to form a pair of intersecting planar surfaces” occurs when implanting/manipulating the resurfacing humeral head implant;
- (iv) Positioning a resurfacing humeral head implant (see Figures 1-14) on the resurfaced surface of the humeral head; and
- (v) Positioning an extended articulating surface (it should be noted that, from the claim language, an arbitrary line or boundary distinguishes/defines the "extended articulating surface") of the resurfacing humeral head implant in a lateral region of the humeral head so as to articulate with at least one of a bone and a ligament and interface with the planar surface. The “step region” could be the material thickness at the end (e.g., periphery) of the “extended articulating surface”.

Response to Arguments

8. With regards to the 102(b) rejection based on Sutter et al. (US 4,328,593 A), Applicant's arguments filed October 31, 2007 have been fully considered but they are not persuasive. The Applicant argues that Sutter et al. '593 does not disclose the extended articulating surface as protruding only from a portion of the resurfacing head. The Examiner respectfully disagrees. The “only from a portion of the resurfacing head” could be broadly interpreted as a side or sides of the resurfacing head. The extended articulating surface of Sutter et al. '593 does extend from the side or sides of the resurfacing head. Further, the Applicant argues that Sutter et al. '593 does not disclose the pair of intersecting planar surfaces as parallel to the hole. The Examiner respectfully

disagrees. The pair of intersecting planar surfaces are parallel to the stem, therefore parallel to the bore formed into the bone.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 5-11, 13-15, 17, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over BIOMET brochure (engineering drawings submitted 7/22/1997, and cited in Applicant's IDS of 12/17/2003) in view of Sutter et al. (US 4,328,593 A).

Referring to Drawings 1-4, the BIOMET brochure discloses a monolithic resurfacing humeral implant comprising:

- (i) A hemispherical exterior articulating surface;
- (ii) A concave interior surface opposite said exterior articulating surface;
- (iii) An integral (i.e., unitary) straight, tapered anchoring device (see drawings) having a textured outer surface (brochure disclosed it as a glass bead blast), said anchoring device extending from said interior surface; and
- (iv) An extended articulating surface protruding from only a portion of said hemispherical exterior articulating surface. The second (i.e., lateral view) and fourth (i.e., main or fourth) drawings show the extended articulating surface as comprising a "step". Regarding claims 26

and 27, the main figure of the brochure clearly shows the hemispherical exterior articulating surface as defining a peripheral base surface, and wherein the extended articulating surface defines an upper surface between the planar surface and the concave interior surface, said upper surface being generally parallel to the base surface (just like Applicant's). The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of, relating to, or lying in a plane". The "extended articulating surface" of the BIOMET implant comprises an interior surface "situated in a plane" or "lying in a plane".

The BIOMET brochure discloses the invention as claimed except for particularly disclosing recently added limitation "a pair of intersecting planar INNER surfaces, said planar surfaces being generally parallel to an integral straight anchoring device and forming a "V" shaped surface". However, this is already known in the art. For example, Sutter et al. disclose a monolithic resurfacing humeral implant comprising an extended articulating surface having a pair of intersecting inner planar surfaces (Figures 1-3, 7, 9, and 10: ribs 3g and grooves 3f; see column 4, lines 47-64; column 5, lines 32-53), said planar inner surfaces being generally parallel to an integral straight anchoring device (clearly seen in Figures 1-3; see column 4, lines 47-64; column 5, lines 32-53) and forming a "V" shaped surface (see Figures 2 and 7) in order to permit the monolithic resurfacing humeral implant to be firmly and durably secured without cement (among other advantages; see Abstract; see column 4, lines 47-64; column 5, lines 32-53).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a monolithic resurfacing humeral implant comprising an extended articulating surface having a pair of intersecting planar inner surfaces, said planar surfaces being generally parallel to an integral straight anchoring device and forming

“V” shaped surface, as taught by Sutter et al., with the monolithic resurfacing humeral implant of the BIOMET brochure, in order to permit the monolithic resurfacing humeral implant to be firmly and durably secured without cement.

NOTE: Looking to Applicants’ specification (see paragraphs 0022 and 0027), there is no criticality in the use of a “planar “V” shaped inner surface”. Furthermore, the Applicant admits in the present application that “the resection 52 may be of various other shapes or configurations” (see paragraph 0027).

Response to Arguments

11. With regards to the 103(a) rejection based on BIOMET brochure (engineering drawings submitted 7/22/1997, and cited in Applicant’s IDS of 12/17/2003) in view of Sutter et al. (US 4,328,593 A), Applicant’s arguments filed October 31, 2007 have been fully considered but they are not persuasive. The Applicant argues that the BIOMET brochure does not show the limitations of claims 26/27. The Examiner respectfully disagrees.

a. The term “planar” does not exclusively means “flat” (as Applicant argues). The term “planar” is generally defined as: “Of, relating to, or situated in a plane”; “of, relating to, or lying in a plane”.

b. The BIOMET brochure clearly shows a flange or extended articulating surface protruding/extending from only a portion of said hemispherical exterior articulating surface. Further, the main figure of the BIOMET brochure clearly shows the hemispherical exterior articulating surface as defining a peripheral base surface, and wherein the extended articulating

surface defines an upper surface between the pair of planar surfaces and the concave interior surface, said upper surface being generally parallel to the base surface (just like Applicant's).

c. The combination of the teachings of the BIOMET brochure and Sutter et al. '593 results in a humeral implant comprising a flange or extended articulating surface protruding/extending from only a portion of a hemispherical exterior articulating surface, which extended articulating surface comprises a pair of inner intersecting planar surfaces forming a "V-shaped" inner surface.

12. Claims 1-3, 6-13, 15, 17, 19-22, 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Long et al. (US PG Pub No 2004/0193277 A1) in view of Sutter et al. (US 4,328,593 A).

Referring to Figures 7-23, Long et al. disclose a monolithic resurfacing humeral implant comprising:

- (i) A hemispherical exterior articulating surface (first body articulating surface 24);
- (ii) A concave interior surface (interior surface of first body 22) opposite said exterior articulating surface;
- (iii) An integral (i.e., unitary) straight, tapered anchoring device (stem 36) having a textured outer surface (see blasted surface shown in Figure 10), said anchoring device extending from said interior surface; and
- (iv) An extended articulating surface (second body articulating surface 32 of second body 30) protruding from only a portion of said hemispherical exterior articulating surface, said extended articulating surface having at least one planar interior surface. Regarding claims 26 and 27, the

Figures clearly shows the hemispherical exterior articulating surface as defining a peripheral base surface, and wherein the extended articulating surface defines an upper surface between the planar surface and the concave interior surface, said upper surface being generally parallel to the base surface (just like Applicant's). The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of, relating to, or lying in a plane". The "extended articulating surface" of the Long et al. implant comprises an interior surface "situated in a plane" or "lying in a plane". Long et al. also disclose the method as claimed in claims 19-22 and 24 (see pages 4-6), including resecting the humeral head to form planar surfaces.

Long et al. disclose the invention as claimed except for particularly disclosing recently added limitation "a pair of intersecting planar surfaces, said planar surfaces being generally parallel to an integral straight anchoring device and forming a "V" shaped surface". However, this is already known in the art. For example, Sutter et al. disclose a monolithic resurfacing humeral implant comprising an extended articulating surface having a pair of intersecting inner planar surfaces (Figures 1-3, 7, 9, and 10: ribs 3g and grooves 3f; see column 4, lines 47-64; column 5, lines 32-53), said planar surfaces being generally parallel to an integral straight anchoring device (clearly seen in Figures 1-3; see column 4, lines 47-64; column 5, lines 32-53) and forming a "V" shaped surface (see Figures 2 and 7) in order to permit the monolithic resurfacing humeral implant to be firmly and durably secured without cement (among other advantages; see Abstract; see column 4, lines 47-64; column 5, lines 32-53). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a monolithic resurfacing humeral implant comprising an extended articulating surface having a pair of intersecting inner planar surfaces, said planar

surfaces being generally parallel to an integral straight anchoring device and forming a “V” shaped surface, as taught by Sutter et al., with the monolithic resurfacing humeral implant of Long et al., in order to permit the monolithic resurfacing humeral implant to be firmly and durably secured without cement.

NOTE: Looking to Applicants’ specification (see paragraphs 0022 and 0027), there is no criticality in the use of a “planar “V” shaped inner surface”. Furthermore, the Applicant admits in the present application that “the resection 52 may be of various other shapes or configurations” (see paragraph 0027).

13. Claim 5 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Long et al. (US PG Pub No 2004/0193277 A1), as modified by Sutter et al. (US 4,328,593 A), and further in view of Copeland™ Humeral Resurfacing Head (Biomet Orthopedics, Inc.: 2000 brochure).

Long et al., as modified by Sutter et al., disclose the invention as claimed in claims 1-3, 6-13, 15, 17, 19-22, 24, 26, and 27. Long et al. did not particularly disclose the stem as having flutes. However, this is well known in the art. For example, the Copeland brochure discloses a monolithic resurfacing humeral implant comprising a tapered post having flutes/ribs in order to improve the mechanical press-fit and prevent rotation of said implant. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a monolithic resurfacing humeral implant comprising a tapered post having flutes/ribs, as taught by the Copeland brochure, with the monolithic resurfacing humeral implant of Long et al., in order to improve the mechanical press-fit and prevent rotation of said implant.

Response to Arguments

14. With regards to the 103(a) rejection based on Long et al. (US PG Pub No.2004/0193277 A1) in view of Sutter et al. (US 4,328,593 A), Applicant's arguments filed October 31, 2007 have been fully considered but they are not persuasive.

a. The term "planar" does not exclusively means "flat" (as Applicant argues). The term "planar" is generally defined as: "Of, relating to, or situated in a plane"; "of, relating to, or lying in a plane".

b. Both, Long et al. (PG Pub No 2004/0193277 A1) AND Sutter et al. (US 4,328,593 A), disclose resecting/resurfacing a humeral head and forming at least one planar surface. The resurfacing disclosed by Sutter et al. results in a pair of intersecting planar surfaces, which pair of intersecting planar surfaces are parallel to a hole/bore formed in the resurfaced/resected head (see Figures).

c. The combination of the teachings of Long et al. (PG Pub No 2004/0193277 A1) and Sutter et al. '593 results in a humeral implant comprising a flange or extended articulating surface protruding/extending from only a portion of a hemispherical exterior articulating surface, which extended articulating surface comprises a pair of inner intersecting planar surfaces forming a "V-shaped" inner surface.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Javier G. Blanco
January 15, 2008

A large, stylized handwritten signature in black ink, consisting of a large 'J' and 'B' followed by a long horizontal stroke.A handwritten signature in black ink, appearing to read 'David H. Willse'.

David H. Willse
Primary Examiner